Docket No.: 2343-179-27

IN THE UNITED STATES

ROUP ART UNIT: 1643

IN RE APPLICATION: MARK L. LAWRENCE, E

SERIAL NUMBER:

10/767,441

AUG 1 7 2004 AMINER: UNASSIGNED **JANUARY 30, 2004** FILED:

FOR: USE OF NOVEL VIRULENCE-SPECIFIC GENES FOR DIAGNOSIS AND POTENTIAL CONTROL OF

VIRULENT STRAINS OF LISTERIA MONOCYTOGE

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. 1.97

Assistant Commissioner for Patents PO BOX 1450 **ALEXANDRIA, VA 22313-1450**

Sir:

Applicant(s) wish(es) to disclose the following information.

REFERENCES

Applicant(s) wish(es) to make of record the documents listed on the attached Form PTO-1449. Copies of the listed documents are attached, where required, as are either statements of relevancy or any readily available full or partial English translations of any non-English-language documents.

RELATED CASES

Attached is a list of Applicant's(s') pending applications and issued patents which may be related to the present application. Copies of the documents, where required, are attached along with Form PTO-1449.

CERTIFICATION

The undersigned certifies that

- each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application for the first time (to the knowledge of the undersigned, having made reasonable inquiry) not more than three months prior to the filing of this statement.
- \Box no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.

BASIS FOR CONSIDERATION

This Information Disclosure Statement is filed:

- \Box without fee and within three months of the filing date of the application.
- without fee and within three months of the date of entry of the U.S. national stage.
- without fee and before the mailing date of a first Office Action on the merits (to the knowledge of the undersigned).
- without fee and with the appropriate certification above.
- without fee and with a new CPA application.
- \Box without fee and with a Request for Continued Examination.
- with fee and before the mailing date of any Final Office Action, Notice of Allowance or an action that otherwise closes prosecution (to the knowledge of the undersigned).
- with fee, appropriate certification above, and before payment of the Issue Fee.

DEPOSIT ACCOUNT

Please charge any additional fees for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to Deposit Account No. 50-1442.

Respectfully submitted,

PIPER RU

Steven B Kelber Attorney of Record Registration No. 30,073

Rerry E. Van Over Registration No. 42,197

1200 Nineteenth Street, N.W. Washington, DC 20036-2412 Telephone No. (202) 861-3900 Facsimile No. (202) 223-2085

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| | AF | Aznar, et al., "On the specificity of PCR detection of <i>Listeria monocytogenes</i> in food: a comparison of published primers." System Appl. Microbiol., 25:109-119 (2002). | | | | | : a | |
| | AG | Bassler, et al., "Use of a fluorogenic probe in a PCR-based assay for the detection of <i>Listeria monocytogenes</i> ." Applied and Environmental Microbiology, 61(10):3724-3728 (1995). | | | | | | |
| | АН | Blais, et al., "A nucleic acid sequence-based amplification system for detection of <i>Listeria monocytogenes hlyA</i> sequences." Applied and Environmental Microbiology, 63(1):310-313 (1997). | | | | | | |
| | AI | Bohne, et al., "Differential regulation of the virulence genes of <i>Listeria monocytogenes</i> by the transcriptional activator PrfA." Molecular Microbiology 20(6):1189-1198 (1996). | | | | | | |
| | AJ | Bubert, et al., "Detection and differentiation of <i>Listeria</i> spp. by a single reaction based on multiplex PCR." Applied and Environmental Microbiology, 65(10):4688-4692 (1999). | | | | | | |
| | AK | Bubert, et al., "Differential expression of <i>Listeria monocytogenes</i> virulence genes in mammalian host cells." Mol Gen Genet 261:323-336 (1999). | | | | | | |
| | AL | Camilli, et al., "Dual roles of <i>plcA</i> in <i>Listeria monocytogenes</i> pathogenesis." Molecular Microbiology 8(1):143-157 (1993). | | | | | | |
| | AM | Carpenter, et al., "Survival of <i>Listeria monocytogenes</i> on processed poultry." Journal of Food Science 54(3):556-557 (1989). | | | | | | |
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| . OTHER REFERENCES | | | (Including Author, Title, Date, Pertinent Pages, Etc.) | | | |
| 5 | Domann, et al., "A novel bacterial virulence gene in <i>Listeria monocytogenes</i> required host cell microfilament interaction with homology to the proline-rich region of vinculing The EMBO Journal 11(5):1981-1990 (1992). | | | | | |
| | AO | Donnelly, et al., "Method Applied and Environmen | elly, et al., "Method for flow cytometric detection of <i>Listeria monocytogenes</i> in milk." ed and Environmental Microbiology, 52(4):689-695 (1986). | | | |
| | AP | Doyle, et al., "Survival of short-time pasteurization (1987). | t al., "Survival of <i>Listeria monocytogenes</i> in milk during high-temperature, ne pasteurization." Applied and Environmental Microbiology, 53(7):1433-1438 | | | |
| | AQ | application to determine | tion of monoclonal antibodies to <i>Listeria monocytogenes</i> and their the virulence of isolates from channel catfish." Applied and blogy, 65(7):2827-2832 (1999). | | | |
| | AR | Erdenlig, et al., "Pathoge monocytogenes isolates f (2000). | al., "Pathogenicity and production of virulence factors by <i>Listeria</i> enes isolates from channel catfish." Journal of Food Protection 63(5):613-619 | | | |
| | AS | Farber, et al., "Thermal resistance of <i>Listeria monocytogenes</i> in sausage meat." Acta Microbiologica Hungarica 36(2-3):273-275 (1989). | | | | |
| | AT | Farber, et al., "Monoclon species and their potentia (1987). | al., "Monoclonal antibodies directed against the flagellar antigens of <i>Listeria</i> d their potential in EIA-based methods." Journal of Food Protection 50(6):479-484 | | | |
| | AU | and noninvasive listerios | nciosa, et al., "Characterization of <i>Listeria monocytogenes</i> strains involved in invasive noninvasive listeriosis outbreaks by PCR-based fingerprinting techniques." Applied and ironmental Microbiology, 67(4), 1793-1799 (2001). | | | |
| | AV | Freitag, et al., "Examination of <i>Listeria monocytogenes</i> intracellular gene expression by using the green fluorescent protein of <i>Aequorea victoria</i> ." Infection and Immunity, 57(4):1844-1852 (1999). | | | | |
| | AW | Gellin, et al., "Listeriosis." JAMA 261(9):1313-1320 (1989). | | | | |
| | AX | Glaser, et al., "Comparative genomics of <i>Listeria</i> species." Science, 294, 849-852 (2001). | | | | |
| | AY | monocytogenes and the L | the pathogenic to the innocuous: comparison of the <i>Listeria</i> he <i>Listeria innocua</i> genomes." GenBank Accession# NC-003210 cbi.nlm.nih.gov, page 1 and 2 of 1,771, printed July 16, 2004. | | | |
| | AZ | Graham, et al., "Inter- an spacer regions of six <i>List</i> 863-869 (1997). | nd intraspecies comparison of the 16S-23S rRNA operon intergenic steria spp." International Journal of Systematic Bacteriology, 47(3), | | | |
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| *EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; draw line through citation | | | | | | |

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| OTHER REFERENCES | | | (Including Author, Title, Date, Pertinent Pages, Etc.) | | | |
| | ВА | Gray, et al., "Listeria mo 30(2):309-373 (1966). | onocytogenes and listeric infections." Bacteriological Reviews, | | | |
| | BB | Heisick, et al., "Listeria : Microbiology, 55(8):192. | spp. found on fresh market produce." Applied and Environmental 5-1927 (1989). | | | |
| | вс | Hof, et al., "Is any strain International Journal of F | y strain of Listeria monocytogenes detected in food a health risk?" mal of Food Microbiology, 16:173-182 (1992). | | | |
| | BD | | detection of viable <i>Listeria monocytogenes</i> by reverse blied and Environmental Microbiology, 63(11): 4441-4448 (1997). | | | |
| | BF | Kuhn, et al., "Molecular Engineering, 17:31-51 (1 | studies on the virulence of <i>Listeria monocytogenes</i> ." Genetic 1995). | | | |
| | BF | Lamont, et al., "Listeria Infection, 17:7-28 (1988) | eria monocytogenes and its role in human infection." Journal of 988). | | | |
| | BG | Lennon, et al., "Epidemic perinatal listeriosis." Pediatric Infectious Disease, 3(1):30-34 (1984). | | | | |
| 2 | вн | Liu, D., "Development of gene probes of <i>Dichelobacter nodosus</i> for differentiating strains causing virulent, intermediate or benign ovine footrot." British Veterinary Journal, 150(5):451-462 (1994). | | | | |
| | BI | Liu, et al., "Dichelobacter nodosus: differentiation of virulent and benign strains by gene probe based dot blot hybridisation." Veterinary Microbiology, 38:71-79 (1993). | | | | |
| | вј | Nishibori, et al., "Correlation between the presence of virulence-associated genes as determined by PCR and actual virulence to mice in various strains of <i>Listeria</i> spp." Microbiol Immunol 39(5), 343-349 (1995). | | | | |
| | BK | Norton, et al., "Detection of viable <i>Listeria monocytogenes</i> with a 5' nuclease PCR assay." Applied and Environmental Microbiology, 65(5):2122-2127 (1999). | | | | |
| | BL | Norton, et al., "Character from the smoked fish ind (2001). | racterization and pathogenic potential of <i>Listeria monocytogenes</i> isolates th industry." Applied and Environmental Microbiology, 67(2):646-653 | | | |
| | ВМ | | genic effects in enterocytelike Caco-2 cells differentiate virulent from s." Journal of Clinical Microbiology, 29(5):990-996 (1991). | | | |
| | BN | Portnoy, et al., "Role of J. Exp. Med.,167:1459-1 | Themolysin for the intracellular growth of <i>Listeria monocytogenes</i> ." 1471 (1988). | | | |
| | во | Portnoy, et al., "Molecul and Immunity, 60(4):126 | alar determinants of <i>Listeria monocytogenes</i> pathogenesis." Infection 263-1267 (1992). | | | |
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| | | OTHER REFERENCES | (Including Author, Title, Date, Perting | nent Pages, E | tc.) | |
| , | Poyart, et al., "The zinc metalloprotease of <i>Listeria monocytogenes</i> is required for matura of phosphatidylcholine phospholipase C: direct evidence obtained by gene complementation." Infection and Immunity, 61(4):1576-1580 (1993). | | | | by gene | |
| | BQ | Roche, et al., "Assessment of the virulence of <i>Listeria monocytogenes</i> : agreement between a plaque-forming assay with HT-29 cells and infection of immunocompetent mice." International Journal of Food Microbiology, 68:33-44 (2001). | | | | |
| | BR | | 'Examination of <i>Listeria monocytogenes</i> in milk products." Acta a Hungarica 36(2-3):259-261 (1989). | | | |
| | BS | Sallen, et al., "Comparative analysis of 16S and 23S rRNA sequences of <i>Listeria</i> species." international Journal of Systematic Bacteriology, 46(3):669-674 (1996). | | | | |
| | вт | Schuchat, et al., "Epidemiology of human listeriosis." Clinical Microbiology Review, 4(2):169-183 (1991). | | | | |
| | BU | Smith, et al., "The two distinct phospholipases C of <i>Listeria monocytogenes</i> have overlapping roles in escape from a vacuole and cell-to-cell spread." Infection and Immunity, 63(11):4231-4237 (1995). | | | | |
| | BV | Vazquez-Boland, et al., "Nucleotide sequence of the lecithinase operon of <i>Listeria monocytogenes</i> and possible role of lecithinase in cell-to-cell spread." Infection and Immunity, 60(1):219-230 (1992). | | | | |
| | BW | Vazquez-Boland, et al., "Listeria pathogenesis and molecular virulence determinants." Clinical Microbiology Reviews, 14(3):584-640 (2001). | | | | |
| | BX | Listeria monocytogenes l | edmann, et al., "Ribotypes and virulence gene polymorphisms suggest three distinct teria monocytogenes lineages with differences in pathogenic potential." Infection and munity, 65(7):2707-2716 (1997). | | | |
| | BY | | apid detection of <i>Listeria monocytogenes</i> by a PCR assay specific for an Molecular and Cellular Probes, 13:127-131 (1999). | | | |
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